

REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claim Amendments

By this Amendment, the proviso of claim 1 is deleted, the process of claim 1 is limited to the process in an industrial scale, the transition language of claim 1 is revised to “consisting essentially of”, and new claim 9 is added.

“In an industrial scale” in claim 1 is supported by the disclosure on page 7, lines 4-8 of the original English specification.

New claim 9 relates to a process for improving a separation-precipitation rate, which is supported by the disclosure of Tables 1, 4, 6, 8, 10 and 12 of the original English specification.

Summary of Interview

Prior to issuing the Advisory Action, the Examiner contacted Applicants’ representative to discuss the above-identified application. During the telephone conversation, the Examiner indicated that the portion of the specification relied upon for support of the “proviso” language refers to a method comprising a cooling step. Accordingly, it is the position of the Examiner and her Supervisor that this disclosure is not sufficient to support the proviso language under 35 U.S.C. § 112, first paragraph.

The Examiner proposed amending the claims to recite “consists of” rather than “comprises”. The Examiner indicated that such an amendment should place the claims in better condition for allowance. Applicants’ representative inquired as to whether replacing the phrase “comprising” with the phrase “consisting essentially of” would be helpful. The Examiner indicated that this language *may* be helpful in placing the claims in better condition for allowance.

Applicants appreciate the Examiner’s helpful comments.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is rendered moot by the cancellation of the proviso language, as discussed above.

Discussion Regarding the Present Invention and Previously Applied Prior Art

The only outstanding rejection in the above-identified application is the written description rejection discussed above. However, in order to advance prosecution of this application, Applicants wish to provide the following comments regarding the present invention, as well as two previously applied U.S. patents.

The present invention proposes a novel fractionation method between 7S globulin and 11S globulin, wherein one object of the present invention is a highly accurate and efficient fractionation method which can be performed in an industrial scale. (Please see page 7, lines 4-8 of the original English specification.) In other words, the present invention provides a method for separating a 7S globulin-rich fraction and an 11S globulin-rich fraction by which a mutual contamination between soluble and insoluble fraction is reduced and by which a production in an industrial scale is accomplished conveniently and efficiently. (Please see page 5, lines 2-7 of the original English specification.) More specifically, the method comprises a heating treatment under acidic conditions, adjusting an ionic strength to 0.02 or more but < 0.2, and adjusting pH of the solution to 4.5 to <5.6. By the method of the present invention, the separation is greatly facilitated with a **higher separation-precipitation rate** of the insoluble fraction. (Please see Tables 1, 4, 6, 8, 10, 12, page 25, lines 7-10, and page 30, lines 3-5, of the original English specification.) **Thus, the present invention provides the excellent and unexpected effect of improving the “separation-precipitation rate” of 11S.**

The Examiner previously applied a combination of Saitoh et al. (US 6,638,562) and Howard et al. (US 4,368,151).

The method of Saitoh et al. comprises a heating treatment under acidic condition, and phytase treatment, and then, separating at pH 5.6-6.6. However, adjustment of an ionic strength is not carried out in Saitoh et al. Comparative Example 2 of the specification (ionic strength: 0.013) corresponds to Saito et al., which falls outside the ionic strength required by Applicants’

claims. When the result of Example 2 of the specification (ionic strength: 0.14) is compared with the result of Comparative Example 2, the ratio of 7S globulin and 11S globulin is almost the same (Table 3), **but the separation-precipitation rate of the insoluble fraction is remarkably improved (Table 4) in Example 2.** Thus, the excellent and unexpected effect of Applicants' invention is not taught or suggested by Saitoh et al.

The method of Howard et al. (US 4,368,151) comprises (A) providing a solution with a sufficient amount of: (i) from about 0.05mM to about 5.0mM sulfite ion; and (ii) water-soluble salt to provide an ionic solution strength ranging from about 0.0005u to about 0.2u; (B) precipitating at least a major weight of said 11S protein from said solution within the pH 5.3-6.3 range; and (C) recovering the precipitated 11S protein from said solution. However, a heating treatment, as required by Applicants' claims, is not carried out in Howard et al. Comparative Example 1 of the specification corresponds to Howard et al. When the result of Example 1 is compared with the result of Comparative Example 1, the ratio of 7S globulin and 11S globulin is almost the same (Table 2), **but the separation-precipitation rate of the insoluble fraction is remarkably improved in Example 1 (Table 1).** Thus, the excellent and unexpected effect of Applicants' invention is not taught or suggested by Howard et al.

The following Table was provided in a previously filed response, and is included again for the Examiner's convenience.

	Presently Claimed Invention	Saitoh et al.	Howard et al.
A. Sulfurous acid compound			○
B. Heating under acidic condition	○	○	
C. Adjustment of an ionic strength	○		○
D. Phytase treatment		○	
E. Separating under acidic condition	○	○	○
Effect	Separating 7S/11S in an industrial scale , Improving separation-precipitation rate of 11S	Separating 7S/11S	Separating 7S/11S

As demonstrated by the Table provided above, neither Saitoh et al. nor Howard et al. teach each of the elements of Applicants' methods, which remarkably and unexpectedly improve the **separation-precipitation rate of the insoluble fraction**, in order to separate 7S globulin and 11S globulin conveniently in an industrial scale. Neither of the previously applied references (Saitoh et al. and Howard et al.) teach or suggest this unexpected result. MPEP 716.02(a)(III) states that the "[p]resence of a property not possessed by the prior art is evidence of nonobviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)." Thus, the improvement of the separation-precipitation rate of the insoluble fraction, as achieved by Applicants' methods, demonstrates the unobviousness of the present claims.

Furthermore, claim 1 has been amended to incorporate "consisting essentially of" language, which limits the scope of the claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. See MPEP 2111.03 and *In re Hertz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

As discussed above, Saitoh et al. fail to teach or suggest adjustment of an ionic strength, as required by Applicants' claims. This deficiency was previously acknowledged by the Examiner, who relied upon Howard et al. as allegedly remedying this deficiency. As discussed in previous responses, Howard et al. disclose a method of separating 7S globulin and 11S globulin **in the presence of sulfite ion**. Specifically, the method comprises: (A) providing to a solution a sufficient amount of: (i) **from about 0.05 mM to about 5.0 mM sulfite ion**; and (ii) water-soluble salt to provide an ionic solution strength ranging from about 0.0005u to about 0.2u; (B) precipitating at least a major weight of said 11S protein from said solution within the pH 5.3-6.3 range; and (C) recovering the precipitated 11S protein from said solution. (Please see claim 1 of Howard et al.)

Thus, the presence of sulfite ion is **essential** for Howard et al. to provide the desired ionic solution strength. Accordingly, the inclusion of sulfite ion would materially affect the basic and novel characteristics of Applicants' claimed method, and is thus excluded by the "consisting essentially of" language of the present claims.

Therefore, one of ordinary skill in the art would not combine the teachings of Saitoh et al. and Howard et al., and arrive at Applicants' claimed invention, particularly since the Howard et al. method employs a step which is specifically excluded by Applicants' claims.

Moreover, even if the teachings of Saitoh et al. and Howard et al. are combined, a skilled person in the art would not arrive at Applicants' presently claimed method, and the unexpected results achieved there from.

Lastly, Applicants have added new claim 9, directed specifically to a process for improving a separation-precipitation rate of an insoluble fraction for separation a soluble fraction containing 7S globulin from the insoluble fraction containing 11S globulin. This method is not taught or suggested by the previously applied references. Thus, consideration and allowance of this claim is respectfully requested.

Conclusion

Therefore, in view of the foregoing amendments and remarks, it is submitted the ground of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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